1081

K083669

510(k) Summary

JUN - 8 2009

1. **Name/Address of Submitter:** **Euroteknika**
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74700, Salanches, France

2. **Contact Person:** **Emmanuel Montini**
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3. **Date Summary Prepared:** November 14, 2008

4. **Devices Name:** Obi

5. **Predicate Devices:**

Intra-Lock Milo (K 050970)	**IMTEC Sendax Mini Dental Implant (MDI) (K 972351)**	**Zimmer (Sulzer Dental / Sulzer Medica) Swiss Plus Conical (K 011245)**	**Intra-Lock MDL (K 070601)**

6. **Devices Description:** A set of root form endosseous dental implants and components for surgical placement in maxillary and/or mandibular arch to support crowns, bridges, overdentures in endentulous or partially edentulous patients.

7. **Intended Use:** The device is intended for surgical placement in mandibular arch to support overdentures in edentulous patients.

8. **Brief Description of Clinical and Non-clinical Testings:** Laboratory testing was conducted to determine device functionality and conformance to design requirements.

9. **Conclusion Drawn:** Substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2009

Euroteknika
C/O Mr. Emanuel Montini
Senior Consultant
BCF Certification Incorporated
1100 Rene-Levesque-Boulevard West-25th Floor
Montreal, Quebec
CANADA H3B 5C9

Re: K083669
Trade/Device Name: OBI
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 25, 2009
Received: May 27, 2009

Dear Mr. Montini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., MA
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083669

Indication for Use

Device Name: OBI

Indication for Use: Surgical placement in mandibular arch to support overdentures in edentulous patients.

Concurrence of CDRH Office of Device Evaluation

Prescription Use __X__ OR Over-the-counter Use ____
(per 21CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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